

REMARKS/ARGUMENTS

In response to the Office Action dated April 21, 2004, in connection with the captioned application, please consider the following remarks. Applicants are also submitting, concurrently herewith, a request for extension of time for one (1) month from July 21, 2004 to August 21, 2004.

Claims 4-6 and 38 are pending in the instant application. The following remarks are believed to be fully responsive to the Office Action.

THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claims 4-6 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the Examiner contends that it is unclear whether the phrase “further comprises an iodinated contrast agent, MRI active agent or ultrasound contrast agent” is defining the “diagnostic effective compound” or is in addition thereto.

In response, Applicants submit that claim 38 has been amended to recite “embolus generating composition” so that it is consistent and clear that the phrase “further comprises an iodinated contrast agent, MRI active agent or ultrasound contrast agent” is an additional part of embolus generating composition as recited in the claim.

Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. 112, second paragraph, has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

Claims 4-6 and 38 are rejected under 35 U.S.C. 102 (b) as being anticipated by Tsuru, U.S. Patent No. 5,055,307 ("Tsuru"). Further, claims 4-6 and 38 are rejected under 35 U.S.C. 102 (a,e) as being anticipated by Morrison, U.S. Patent No. 5,827,531 ("Morrison"). Finally, claims 4-6 and 38 are rejected under 35 U.S.C. 102 (a,e) as being anticipated by Unger, U.S. Patent No. 5,585,112 ("Unger"). In response, Applicants submit that each of the rejections should be withdrawn for the reasons stated below.

A finding of anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genetech Inc.*, 727 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

As currently amended, the present invention claims a method a embolus therapy comprising the steps of introducing into the vasculature of a subject an embolus generating composition having particles selected to generate emboli at a target site within the subject

and detecting the embolus location by a diagnostic technique. The composition includes solid water-insoluble particles 10-20 micrometers in size. The particles consist essentially of either a water insoluble non-radioactive diagnostically effective compound encapsulated in a non-polymeric particulate matrix selected from the group consisting of insoluble metal oxides, insoluble metal salts, inert metals, glass, ceramic particles and porous particles, vesicles encapsulating a non-radioactive diagnostically effective compound, or a solution thereof. The composition further includes an imageable marker formed from an iodinated contrast agent, an MR active agent, or an ultrasound contrast agent to identify the extent of embolization.

Tsuru discloses a slow-release drug delivery granule in which a porous granule contains a drug. The pore size is selected to effect the drug release rate. Tsuru also discloses that a soluble organic polymeric coating may be applied to the granule to further slow drug release rate as the polymeric coating must first dissolve.

Thus, there is no teaching in Tsuru of solid water insoluble compounds encapsulated by a non-polymeric matrix. Furthermore, Tsuru fails to teach or suggest that there is "a non-radioactive diagnostically effective compound encapsulated in a non-polymeric particulate matrix selected from the group consisting of insoluble metal oxides, insoluble metal salts, inert metals, glass, ceramic particles and porous particles, or vesicles encapsulating a non-radioactive diagnostically effective compound, or a solution thereof, and wherein said composition further comprises an iodinated contrast agent, MR active agent, or ultrasound

contrast agent imageable marker to identify the extent of embolization; and detecting the embolus location by a diagnostic imaging technique”.

Further, claims 4-6 and 38 are rejected as anticipated by Morrison. The Examiner asserts that Morrison discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a radio-contrast medium. In response, Applicants respectfully submit that the claim 38 has been amended to remove reference to vesicles. Thus, the rejections should be withdrawn.

Similarly, claims 4-6 and 38 are rejected as anticipated by Unger. The Examiner asserts that Unger discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a ultrasound agent. In response, Applicants respectfully submit that the claim 38 has been amended to remove reference to vesicles. Thus, the rejections should be withdrawn.

In view of the foregoing, claim 38 and the dependent claims are believed to be fully distinguished from Tsuru, Morrison and Unger. Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. 102 has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claims 4-6 and 38 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Unger in view of Tsuru. In response, Applicants submit that each of the rejections should be withdrawn for the reasons stated below.

The Examiner asserts that Unger discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a ultrasound agent. Further, Tsuru teaches a method of embolus therapy using particles and teaches that particles having a size of 10-100 um are especially preferred.

In response, as stated above, Applicants respectfully submit that the claim 38 has been amended to remove reference to vesicles. Thus, the rejections should be withdrawn.

In view of the foregoing, claim 38 and the dependent claims are believed to be fully patentable over Unger in view of Tsuru. Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. 103 has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

CONCLUSION

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,



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